UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MITSUBISHI CHEMICAL CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, ENCYSIVE PHARMACEUTICALS INC., SMITHKLINE BEECHAM PLC AND SMITHKLINEBEECHAM CORP. D/B/A GLAXOSMITHKLINE, Plaintiffs, v. BARR LABORATORIES, INC., Defendant.	Civil Action No. 1:07-CV-11614-JGK **Electronically Filed**

ANSWER AND COUNTERCLAIMS

Defendant Barr Laboratories, Inc. ("Barr"), for its Answer and Counterclaims to the Complaint of Mitsubishi Chemical Corporation ("Mitsubishi"), Mitsubishi Tanabe Pharma Corporation ("Mitsubishi Tanabe"), Encysive Pharmaceuticals Inc. ("Encysive"), and SmithKline Beecham plc and SmithKlineBeecham Corp. d/b/a GlaxoSmithKline (collectively "GSK") (collectively "Plaintiffs"), avers as follows:

Jurisdiction and Venue

1. Barr admits that Plaintiffs purport to state a claim for patent infringement under the patent laws of the United States, arising under 35 U.S.C. §§ 271(e)(2), 271(b), 271(c), and 281-283; purport to base subject matter jurisdiction on 28 U.S.C. §§ 1331 and 1338(a); purport to base venue on 28 U.S.C. §§ 1391(b)-(d) and 1400(b); and purport to base personal jurisdiction on N.Y. C.P.L.R. §§ 301 and 302(a).

The Parties

2. Barr is without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 2 of the Complaint, and therefore denies them.

3. Barr is without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 3 of the Complaint, and therefore denies them.

4. Barr is without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 4 of the Complaint, and therefore denies them.

5. Barr is without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 5 of the Complaint, and therefore denies them.

6. Barr admits that it is a Delaware corporation with a place of business in Pomona, New York; admits that its business includes manufacturing and marketing generic pharmaceuticals; admits that it filed Abbreviated New Drug Application ("ANDA") No. 79-238 as agent for Pliva-Hrvatska d.o.o. ("Pliva"); admits that it is registered with the New York Department of State, Division of Corporations, to do business in New York as a foreign corporation; and denies the remaining averments of paragraph 6 of the Complaint.

7. Barr admits that United States Patent No. 5,214,052 (the "'052 Patent") is entitled "Method for Dissolving Arginineamides and Pharmaceutical Compositions Containing Them"; admits that a copy of the patent is attached to the Complaint as Exhibit A; admits that the face of the patent states that it issued on May 25, 1993 to named inventors Kunihiko Ofuchi and Tatsuo Nomura; admits that the face of the patent states that it was assigned to the Mitsubishi

Kasei Corporation of Tokyo, Japan; and denies the remaining averments of paragraph 7 of the Complaint.

8. Barr admits that Mitsubishi is the recorded assignee of the '052 Patent; admits that the '052 Patent expires on June 30, 2014; admits that a patent term extension was granted pursuant to 35 U.S.C. § 156; and is without knowledge or information sufficient to form a belief as to the truth of the remaining averments of paragraph 8 of the Complaint, and therefore denies them.

9. Barr is without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 9 of the Complaint, and therefore denies them.

10. Barr admits that Food and Drug Administration ("FDA") records indicate that Encysive is the holder of approved new drug application ("NDA") No. 020883 for the drug "argatroban" with the active ingredient "argatroban" in the strength "100 mg/mL" in the dosage form/route of an "injectable/injection" (the "NDA Drug"); and is without knowledge or information sufficient to form a belief as to the truth of the remaining averments of paragraph 10 of the Complaint, and therefore denies them.

11. Barr is without knowledge or information sufficient to form a belief as to the truth of the averments of paragraph 11 of the Complaint, and therefore denies them.

12. Barr denies the averments of paragraph 12 of the Complaint.

The New Drug Application

13. Barr admits that FDA records indicate that NDA No. 020883 was approved on June 30, 2000; and is without knowledge or information sufficient to form a belief

as to the truth of the remaining averments of paragraph 13 of the Complaint, and therefore denies them.

14. Barr admits that the NDA Drug "is indicated as an anticoagulant for prophylaxis or treatment of thrombosis in patients with heparin-induced thrombocytopenia," and denies the remaining averments of paragraph 14 of the Complaint.

COUNT I
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(e)(2)(A) BY DEFENDANT)

15. Barr incorporates by reference its responses to paragraphs 1 through 14 of the Complaint as though fully set forth herein.

16. Barr admits that Barr, as agent for Pliva, submitted ANDA No. 79-238 with the FDA under 21 U.S.C. § 355(j) seeking approval to market "Argatroban Injection, 100 mg/mL, 2.5 mL Vial" (the "ANDA Drug"), and denies the remaining averments of paragraph 16 of the Complaint.

17. Barr admits that the ANDA Drug is considered bioequivalent to the NDA Drug, and denies the remaining averments of paragraph 17 of the Complaint.

18. Barr admits that Barr, as agent for Pliva, submitted ANDA No. 79-238 seeking approval to engage in the commercial manufacture, use, and sale of the ANDA Drug before the expiration of the '052 Patent, and denies the remaining averments of paragraph 18 of the Complaint.

19. Barr admits that by a letter dated November 16, 2007 (the "Notice Letter"), Barr informed Mitsubishi and Encysive that ANDA No. 79-238 was submitted with a

certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV); admits that the Notice Letter was delivered to Mitsubishi and Encysive on or about November 19, 2007; and is without knowledge or information sufficient to form a belief as to the truth of the remaining averments of paragraph 19 of the Complaint, and therefore denies them.

20. Barr admits that the Notice Letter is a "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act"; admits that the Notice Letter states, *inter alia,* that "the '052 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, importation, use or sale of" the ANDA Drug; and denies the remaining averments of paragraph 20 of the Complaint.

21. Barr admits that the Notice Letter states, *inter alia,* that "[e]ach of claims 1-4 of the '052 patent are invalid as obvious under 35 U.S.C. § 103(a) over Tamso Yoshikuni *et al.*, 'Alpha-(N-arylsulfonyl-L-Arginineamides, Process for Their Preparation and Pharmaceutical Composition Containing These Substances,' European Patent Application No. 79103092.7 ('Yoshikuni'), in further view of George M. Krause and John M. Cross, 'Solubility of Phenobarbital in Alcohol-Glycerin-Water Systems,' *Journal of the American Pharmaceutical Association*, Vol. XL:137-139 (1951) ('Krause')"; and denies the remaining averments of paragraph 21 of the Complaint.

22. Barr denies the averments of paragraph 22 of the Complaint.

23. Barr admits that the Notice Letter states, *inter alia,* that "the '052 patent is invalid, unenforceable, and/or will not be infringed by" the ANDA Drug, and denies the remaining averments of paragraph 23 of the Complaint.

24. Barr admits that the Notice Letter states, *inter alia,* that "the '052 patent is invalid, unenforceable, and/or will not be infringed by" the ANDA Drug, and denies the remaining averments of paragraph 24 of the Complaint.

25. Barr admits that the Notice Letter states, *inter alia,* that "any available objective evidence of nonobviousness is insufficient to rebut the *prima facie* case of obviousness," and denies the remaining averments of paragraph 25 of the Complaint.

26. Barr denies the averments of paragraph 26 of the Complaint.

27. Barr denies the averments of paragraph 27 of the Complaint.

28. Barr denies the averments of paragraph 28 of the Complaint.

29. Barr denies the averments of paragraph 29 of the Complaint.

COUNT II
(INDUCEMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(b) BY DEFENDANT)

30. Barr incorporates by reference its responses to paragraphs 1 through 29 of the Complaint as though fully set forth herein.

31. Barr denies the averments of paragraph 31 of the Complaint.

32. Barr denies the averments of paragraph 32 of the Complaint.

33. Barr denies the averments of paragraph 33 of the Complaint.

34. Barr denies the averments of paragraph 34 of the Complaint.

35. Barr denies the averments of paragraph 35 of the Complaint.

COUNT III
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 5,214,052 UNDER 35 U.S.C. § 271(c) BY DEFENDANT)

36. Barr incorporates by reference its responses to paragraphs 1 through 35 of the Complaint as though fully set forth herein.

37. Barr denies the averments of paragraph 37 of the Complaint.

38. Barr denies the averments of paragraph 38 of the Complaint.

39. Barr denies the averments of paragraph 39 of the Complaint.

40. Barr denies the averments of paragraph 40 of the Complaint.

41. Barr denies the averments of paragraph 41 of the Complaint.

42. Barr denies the averments of paragraph 42 of the Complaint.

43. Barr denies the averments of paragraph 43 of the Complaint.

44. Barr denies the averments of paragraph 44 of the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

Barr's manufacture, use, offer for sale, sale, and/or importation of the ANDA Drug pursuant to ANDA No. 79-238 has not directly infringed, does not directly infringe, and will not directly infringe any valid claim of the '052 Patent.

SECOND AFFIRMATIVE DEFENSE

Barr's manufacture, use, offer for sale, sale, and/or importation of the ANDA Drug pursuant to ANDA No. 79-238 has not induced infringement, does not induce infringement, and will not induce infringement of any valid claim of the '052 Patent.

THIRD AFFIRMATIVE DEFENSE

Barr's manufacture, use, offer for sale, sale, and/or importation of the ANDA Drug pursuant to ANDA No. 79-238 has not contributorily infringed, does not contributorily infringe, and will not contributorily infringe any valid claim of the '052 Patent.

FOURTH AFFIRMATIVE DEFENSE

The claims of the '052 Patent are invalid for failure to comply with the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq*.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim against Barr upon which relief can be granted.

COUNTERCLAIM FOR DECLARATORY JUDGMENT

Defendant and Counterclaim Plaintiff Barr, by its undersigned counsel, as and for its counterclaims against Plaintiffs and Counterclaim Defendants Mitsubishi, Mitsubishi Tanabe, Encysive, and GSK, avers as follows:

Jurisdiction and Venue

1. This counterclaim arises under the Declaratory Judgment Act and the Patent Laws of the United States, more particularly under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 1 *et seq.*, respectively. This Court has subject mater jurisdiction pursuant to

28 U.S.C. §§ 1338 and 2201. Venue for these Counterclaims is proper under 28 U.S.C. §§ 1391(b)-(d) and 1400(b). Personal jurisdiction is proper under C.P.L.R. §§ 301 and 302(a).

2. An actual and justiciable controversy exists between Barr and Plaintiffs as to the infringement and validity of the patents in suit, as evidenced, *inter alia*, by the Complaint and Answer in this action.

The Parties

3. Barr is a Delaware corporation with a principal place of business in Pomona, New York, and is registered with the New York Department of State, Division of Corporations, to do business in New York as a foreign corporation.

4. Upon information and belief, based on the allegations of the Complaint, Mitsubishi is a Japanese corporation having its corporate headquarters and principal place of business in Tokyo, Japan.

5. Upon information and belief, based on the allegations of the Complaint, Mitsubishi Tanabe is a Japanese corporation having its corporate headquarters and principal place of business in Osaka, Japan.

6. Upon information and belief, based on the allegations of the Complaint, Encysive is a Delaware corporation having its corporate headquarters and principal place of business in Houston, Texas.

7. Upon information and belief, based on the allegations of the Complaint, SmithKline Beecham plc is an English company having its registered office in Brentford,

England, and SmithKline Beecham Corp. is a Pennsylvania corporation having a principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania.

The Abbreviated New Drug Application

8. Barr, as agent for Pliva, filed ANDA No. 79-238 with the FDA seeking approval for the ANDA Drug. ANDA 79-238 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that the '052 Patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the ANDA Drug.

COUNT I

Declaratory Judgment Of Invalidity Of The '052 Patent

9. The claims of the '052 Patent are invalid for failure to comply with the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq*.

PRAYER FOR RELIEF

WHEREFORE, Barr prays that the Court enter judgment against Plaintiffs:

A. Denying all relief sought in the Complaint, and dismissing the complaint with prejudice;

B. Declaring that the claims of the '052 Patent are invalid, unenforceable, or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the ANDA Drug pursuant to ANDA No. 79-238;

C. Enjoining Plaintiffs, their assigns, and all those in privity therewith from asserting the '052 Patent against Barr, or any of its customers or suppliers;

D. Awarding Barr its attorneys' fees pursuant to 35 U.S.C. § 285, and its costs and expenses; and

E. Awarding Barr such other and further relief as may be just and proper.

Dated: New York, N.Y.
February 11, 2008

s/ Thomas J. Meloro
Thomas J. Meloro, Esq.
Diane C. Ragosa, Esq.
Heather M. Schneider, Esq.
WILLKIE FARR & GALLAGHER LLP
787 Seventh Avenue
New York, NY 10019-6099
(212) 728-8000 Telephone
(212) 728-8111 Facsimile
TMeloro@willkie.com

Attorneys for Defendant Barr Laboratories, Inc.